UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

FERRING PHARMACEUTICALS INC.,	)	
Plaintiff and Counterclaim-Defendant,	)	
v.	)	Civil Action No. 13-cv-12553-NMG
BRAINTREE LABORATORIES, INC.,	)	
Defendant and Counterclaim-Plaintiff.	)	

DECLARATION OF JOSHUA L. SOLOMON

I, Joshua L. Solomon, being duly sworn, depose and say:

1. I am a member in good standing of this bar and an attorney at Pollack Solomon Duffy LLP, which represents Braintree Laboratories, Inc. in this action.

2. I have personal knowledge of the facts presented in this Declaration. I respectfully submit this declaration in support of Braintree's Reply in Support of Its Motion for Summary Judgment.

3. In its opposition to Braintree's Motion for Summary Judgment, Ferring Pharmaceuticals Inc. asserts that the drug Prepopik and Pico-Salax are not the same, and that Ferring's public statement to the contrary was mistaken. Ferring's press release, however, is not the only place where Prepopik and Pico-Salax have been equated.

4. For example, attached hereto as Exhibit 1 is a copy of the FDA's Clinical Pharmacology and Biopharmaceutics Review, which I obtained from the FDA's "Drug Approval

Package" for Prepopik, publicly available on the FDA's website.[1] That document states, in § 1.3, as follows:

> Dose Selection:
>
> The sponsor [Ferring] did not conduct a dose finding study. The two proposed dosing regiments were studied in two phase 3 trials, which were the same regimens as those approved in Canada.

5. Similarly, the FDA's Clinical Pharmacology and Biopharmaceutics Review further states in § 2.2.6, under the heading "What is the sponsor's dose selection rationale?":

> In this submission, the sponsor did not conduct a dose ranging study. The two proposed dosing regimens were studied in two phase 3 trials, which were the same regimens as those approved in Canada.

6. The FDA's Clinical Pharmacology and Biopharmaceutics Review also states the following in § 2.2.5, under the heading "What is the regulatory background?":

> This product [Prepopik] is approved for use for colon cleansing in Europe and Canada under the names of Picolax, PicoSalax or Pico-Salax. In this submission, the sponsor is seeking an approval of this product in the United States for the same indication.

7. Attached hereto as Exhibit 3 is the FDA's Statistical Review, another document that I obtained from the FDA's Drug Approval Package for Prepopik, which is available on the FDA's website. The Statistical Review states as follows in § 2:

> The PicoPrep formulation contains the same 3 active ingredients (sodium picosulfate, magnesium oxide and citric acid) in the same milligram proportions as products sold for more than 3 decades under the trade names Picolax and Picosalax/Pico-Salax, also manufactured by Ferring. Picolax and Picosalax/Pico-Salax are currently approved for use and marketed in 10 countries including the

[1] The Clinical Pharmacology and Biopharmaceutics Review, and other documents in the Drug Approval Package for Prepopik, refer to the drug as "Picoprep." As another document in the FDA's Drug Approval Package explains, Picoprep was the original name that Ferring proposed to the FDA, before changing the name to Prepopik. *See* Summary Review § 12, which is attached hereto as Exhibit 2, and which I also obtained from the FDA's Drug Approval Package for Prepopik, publicly available on the FDA's website ("DMEPA [Division of Medication Error Prevention and Analysis] conducted name reviews and determined that the applicant's original proposed name, Picoprep, was unacceptable. The applicant submitted a request for review of an alternative proposed name, Prepopik, which DMEPA concluded was acceptable.").

United Kingdom (1980), Ireland (1983), Canada (2004), Malta (FE2009), Austria (2010), Czech Republic (2010), Denmark (2010), Germany (2010), Portugal (2010), and Norway (2010) and, although not yet marketed, has been approved in 23 additional countries.

SIGNED UNDER THE PAINS AND PENALTIES OF PERJURY ON JUNE 9, 2014

/s/ Joshua L. Solomon
Joshua L. Solomon

CERTIFICATE OF SERVICE

I hereby certify that this document filed through the ECF system will be sent electronically to the registered participants as identified on the Notice of Electronic Filing ("NEF") on June 9, 2014.

/s/ Matthew B. Arnould
Matthew B. Arnould (BBO#675457)